



June 11, 2008

Scott Gilliam
Indiana State Department of Health
Food Protection Program Suite 5C
2 N. Meridian Street
Indianapolis, IN 46204
Phone number 317/233-7360
fax number 317/233-7334

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JUN 12 2008
Food Protection Program
Indiana State Dept. of Health

RE: fREAL! Foods, LLC Variance Request

Dear Scott,

Thank you for bring the Indiana code concerns regarding Section 410 IAC 7-24-296(c) to our attention. fREAL! Foods would like to request consideration by your department for an alternative cleaning frequency. Attached is the variance request application.

Within the variance request, I am happy to provide the additional information you requested regarding the cleaning and sanitizing frequency recommended by fREAL! Foods. As you'll see, we have conducted significant and rigorous testing to show compliance with a cleaning and sanitizing frequency of once per 24 hours.

Since you may not be familiar with our equipment, I would also like to take this opportunity to describe our equipment and blending process for you. Unlike conventional ice cream freezers, the blending chamber of our blender does not hold chilled ice cream mix and our beverages do not come in bulk quantities. Our pasteurized product is prepackaged in a single serve cup by our state certified dairies. The beverages are stored in a grab-n-go freezer. Our consumers select the beverage cup from the freezer, open the individually packaged lid, and then place the cup into the fREAL! blender. The beverage moves into the blending chamber, completes its blend cycle, and descends to the home position where it is removed and enjoyed. The blender then automatically rinses and sanitizes the blending components and blending chamber to prepare for the next consumer. A video is available on our website that demonstrates the blender cleaning and sanitizing cycle. All this information is listed in the body of the application in the answer to question 5.

By virtue of the equipment's sanitary design, the action of the sanitizer rinse, the test results and the once per 24 pour manual cleaning and sanitation conducted by store personnel, fREAL! Foods is confident the attached information will support the requested alternative cleaning and sanitizing frequency that could be granted by your department.

I look forward to your responds. Please feel free to contact me directly at (925) 255-7014 or at rkarpeles@freal.com

Sincerely,

Rachelle Karpeles
Associate Director of Quality
fREAL! Foods



Request For Variance

State Form 51184 (12/02)

Food Protection Program

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JUL 01 2008

INDIANA STATE DEPARTMENT OF HEALTH

Telephone: 317/233-7360

FAX: 317/233-7334

1. Individual Submitting Request:

Date: 06/11/2008

Name: Rachelle Karpelcs Telephone: (925) 255-7019 Fax: (925) 253-8560
Mailing Address: 37 Avenida de Orinda Email: rkarpelcs@freal.com
Number & Street City State Zip Code
Orinda CA 94563
P.O. Box

2. Person/Organization Seeking Variance:

Name: F'REAL Foods Email:
Mailing Address: 37 Avenida de Orinda
Number & Street City State Zip Code
Orinda CA 94563
P.O. Box

3. Food Establishment(s) for Which Variance is Sought

Include the following information for each food establishment: (List here or attach additional pages if necessary)

- Physical Location (if different than mailing address): please see the attached list
- Mailing Address: Same as list above
(Number, Street, City, State, & Zip Code)
- Telephone Number: () Same as list above Fax Number: ()
- Person at each retail food establishment most responsible for supervising: Store Manager

4. State how the proposal varies from each rule requirement, citing relevant rule sections by number:

(Attach additional pages if necessary)

Per Section 410 IAC 7-24-296

Please see Attachment #4.

5. Explain how the potential public health hazards and/or nuisances will be alternatively addressed by the proposal. Include supporting studies, Hazard Analysis Critical Control Point (HACCP) Plan(s), standard sanitation operating procedures, and/or any other evidence: (Attach additional pages, if necessary.)

Please see Attachment #5. (point 5)

6. List how the proposal demonstrates the following (if applicable to the request):

A) How the proposal differs from what is common and usual in similar industry situations:

B) How the proposal is unique and not addressed in existing rules or law:

C) How the proposal does not diminish the protection of public health:

D) How the proposal is based on new scientific or technological principle(s):

E) How the implementation of the variance would be practical:

Please see attachment 6.

7. Explain how the person/organization seeking the variance will assure that all provisions of a granted variance will be enacted at each food establishment for which a variance has been granted:

Please see attachment 7.

Each establishment performs F'REAL Foods blender cleaning and sanitizing every 24 hours.

8. List all affected parties known by the person/organization seeking a variance, including all affected regulatory authorities: (Attach additional pages if necessary)

Please see attachment 8.

Indiana state store list is attached.

9. Attach copies of any related variances, waivers or opinions issued by other governmental agencies. Please see attachment

For Office Use Only

10. Signature of Individual Making Request:

Printed Name, Title:

Rachelle Karpel

Rachelle Karpel, Associate

Director of Quality



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Food Protection Program
Indiana State Dept. of Health

Request for Variance
State Form 51184 (12/02)
Food Protection Program

1. Individual Submitting Request:

Date 06/11/2008

Name: Rachelle Karpeles Telephone: (925) 255- 7014 FAX: (925) -253-8560
Mailing Address: 37 Avenida de Orinda
Email: rkarpeles@freal.com
City: Orinda Calif. 94563

2. Person/Organization Seeking Variance:

Name: f'REAL! Foods
Mailing Address: 37 Avenida de Orinda, Orinda California 94563

3. Food Establishments(s) for which variance is Sought

- Physical Location: Please see the attached list of establishment's currently selling f'REAL! Foods frozen beverages.
- Mailing Address: Same as above
- Telephone Number: Same as above
- Person at each retail food establishment most responsible for supervising: Store manager

4. State how the proposal varies from each rule requirement, citing relevant rule sections by number:

Per Section 410 IAC 7-24-296:

Equipment food-contact surfaces and utensils; cleaning frequency:

Section 296(c): "except as specified in subsection (d), if used with potentially hazardous food, equipment food-contact surfaces and utensil shall be cleaned throughout the day at least every four (4) hours".

F'REAL! Frozen beverage blender, Model FRLB2-S is designed to only require manual clean and sanitizing once every 24 hours.

5. Explain how the potential public health hazards and/or nuisances will be alternatively addressed by the proposal. Include supporting studies, Hazard Analysis Critical Control Point (HACCP) Plan(s), Standard sanitation operating procedures, and/or any other evidence: (Attach additional pages, if necessary.)



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As background information, the blender equipment is NSF 8 approved. After each pre-pasteurized frozen beverage is blended, and the blending cycle is complete, the serving cup descends to the home position where it may be removed and enjoyed. The blender then automatically rinses the blending components and blending chamber. The equipment is then ready to blend the next frozen beverage for the next customer.

To better understand the blender cleaning and sanitizing cycles, please view the video available on our website designed specifically for our health inspectors. The video can be accessed via the first link under the question – How is the equipment cleaned and sanitized?

<http://www.freal.com/health/main.htm>

The user name: health
Password: milkshake1

fREAL! Foods has conducted significant and rigorous testing to show compliance with a cleaning and sanitizing frequency of once per 24 hours. Attached are three documents associated with the request for an alternative cleaning and sanitizing frequency based on Section 410 IAC 7-24-296(c).

1. The first document (fREAL! Blender Cleaning and Sanitizing Instructions) explains the cleaning and sanitizing protocol followed by store employees every 24 hours.
2. The second document (NFL Coliform Contamination Report) reviews the data and results of an in-laboratory challenge study.
3. The third document (NFL Sanitation Field Tests) reviews the data and results of equipment operation as sampled in the field.

There have been no complaints relating to this issue from the public, or issues raised from the state or local inspectors related to cleaning issues on this unit. There are over 3,000 blenders in the stores across the United States and currently sell over 10 million cups per year.

The unit will be used only for the intended purpose with the intended product.

By virtue of the equipment's sanitary design, the action of the post-blend rinse, the test results, and the once per 24-hour manual cleaning and sanitation conducted by store personnel, we feel confident in requesting an alternative cleaning and sanitizing frequency.

6. List how the proposal demonstrates the following (if applicable to the request):

A) How the proposal differs from what is common and usual in similar industry situations:



The fREAL! Foods blender is patented equipment. There are no other similar situations in the industry. The sanitary design and post blending cleaning feature are unique. In addition the beverage is a prepackaged, single serve item, frozen, and is not stored within the equipment.

B) How the proposal is unique and not addressed in existing rules or law:

Please see the answer to question 6A.

C) How the proposal does not diminish the protection of public Health:

Please see the three documents referenced in answer to question #5.

D) How the proposal is based on a new scientific or technological principles(s):

Please see the three documents referenced in answer to question #5.

E) How the implementation of the variance would be practical:

By virtue of the equipment's sanitary design, the action of the post-blend rinse, the test results, and the once per 24-hour manual cleaning and sanitation conducted by store personnel is sufficient.

7. Explain how the person/organization seeking the variance will assure that all provisions of a granted variance will be enacted at each food establishment for which a variance has been granted:

Each establishment performs fREAL! Foods blender manual cleaning and sanitizing every 24 hours.

8. List all affected parties known by the person/organization seeking a variance, including all affected regulatory authorities:

Indiana State Store list is attached.

9. Attach copies of any related variances, waivers or opinions issued by other governmental agencies.

As an example of the Wisconsin variance is attached

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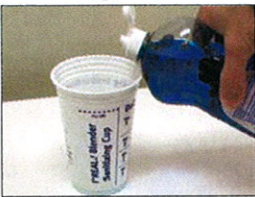
fREAL! Blender Cleaning and Sanitizing Instructions



1. Gather required items for Cleaning and Sanitizing. Ensure fREAL! Brush is in good condition. If it is not, replace it with new one.
Notice: Only use fREAL! Brush on fREAL! Blender



2. Thoroughly wash hands with soap and warm water.



3. Put 2-3 squirts of dishwashing liquid into fREAL! Sanitizing Cup and fill cup about half way with hot water.



4. Open blender front door to access blending chamber by pulling on metal tab located under right corner of door.
Do not turn blender power off during cleaning and sanitizing.



5. Using clean fREAL! Brush dipped frequently in Sanitizing Cup with prepared dishwashing solution, thoroughly clean in the following order:



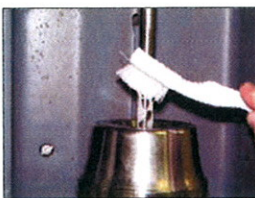
5a. First, the top and underside of metal cup lid;

This is the most important step in the entire process, so be sure to do it thoroughly every time.



5b. Then the top and bottom of blending disc and slider;

(Lift cup lid to access blending disc. Beware of sharp edges.)



5c. Then the blending shaft;



5d. Then the gray plastic blending chamber walls and front door liner;



5e. Then the clear plastic flip up doors - top and bottom, taking care not to press them fully open without supporting them, as this can cause their return springs to break off;



5f. And last, the interior bottom area of gray plastic blending chamber.

(Do this step last to avoid possible spreading of drain area material onto other cleaned surfaces.)



6. Close front door firmly. Blender will automatically rinse off cleaned components.



7. Rinse out and then fill fREAL! Sanitizing Cup to fill line with room temperature water. Add 4-6 drops of BTF Iodophor Sanitizer to room temperature water cup. Sanitizing solution is still nearly clear when properly prepared.



8a. Place Sanitizing Cup with properly prepared sanitizing solution in blender cup holder.



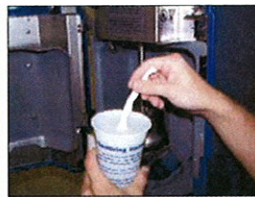
8b. Press and hold both "Less Thick" and "More Thick" buttons for 5 seconds to begin sanitize cycle.



9. While 2 minute sanitize cycle counts down, clean fREAL! Brush and hands again with dishwashing liquid to ensure they are as clean as possible for step 11, and then thoroughly rinse with warm water.



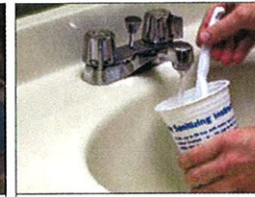
10. When sanitize cycle ends, remove Sanitizing Cup from cup holder, and open front door of blender again.



11 a & b. Use cleaned fREAL! Brush dipped in Iodophor sanitizer solution from Sanitizing Cup to thoroughly apply sanitizing solution to underside and top of metal cup lid like shown in Step 5a.



12 & 13. Pour remaining sanitizing solution down blender's internal drain located in gray plastic blending chamber. Then close front door firmly.



14. Rinse fREAL! Brush and Sanitizing Cup thoroughly with hot water. Allow to dry and save for next day's use.

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f'REAL! Blender Cleaning and Sanitizing Instructions

f'REAL! Blender must be cleaned and sanitized every 24 hours as follows:

1. Gather: f'REAL/ Sanitizing Cup, a clean f'REAL/ Brush in good condition*, dishwashing liquid, and BTF Iodophor Sanitizer bottle or equivalent quaternary sanitizer approved by f'REAL/.
 2. Thoroughly wash hands with soap and warm water.
 3. Put 2 – 3 squirts of dishwashing liquid into f'REAL/ Sanitizing Cup and fill cup about half way with hot water.
 4. Open blender front door to access blending chamber by pulling on metal tab located under right corner of door. (Do not turn blender power off. Power must remain on for blender to recognize cleaning has been done properly).
 5. Using clean f'REAL/ Brush dipped frequently in Sanitizing Cup with prepared dishwashing solution, thoroughly clean in the following order:
 - a. First, the top and underside of metal cup lid. (Lift lid up along shaft to thoroughly clean underside of lid. This is the most important step in the entire process, so be sure to do it thoroughly every time.);
 - b. Then the top & bottom of blending disc and slider. (Lift lid to access blending disc. Beware of sharp edges.);
 - c. Then the blending shaft;
 - d. Then the gray plastic blending chamber walls and front door liner;
 - e. Then the clear plastic flip-up doors—top and bottom, taking care not to press them fully open without supporting them, as this can cause their return springs to break off;
 - f. And last, the interior bottom area of the gray plastic blending chamber. (Do this step last to avoid possible spreading of drain area material onto other cleaned surfaces.)
 6. Close front door firmly. Blender will automatically rinse off cleaned components.
 7. Rinse out f'REAL/ Blender Sanitizing Cup with room temperature water and fill with room temperature water to Fill Line on Sanitizing Cup. Then add 4 -6 drops of BTF Iodophor Sanitizer to room temperature water in Sanitizing Cup. (Or substitute approved quaternary sanitizer diluted to 200 ppm in cup.) 4 -6 drops from spout of BTF Iodophor Sanitizer bottle is all that is needed to reach proper concentration. Sanitizing solution is still nearly clear when properly prepared **
 8. Run 2-minute sanitize cycle:
 - a. Place Sanitizing Cup with properly prepared sanitizing solution in blender cup holder;
 - b. Press and hold both "Less Thick" & "More Thick" buttons for 5 seconds to begin sanitize cycle.
- Note:** Do not use chlorine based sanitizers on blender. Chlorine sanitizers can cause serious damage to f'REAL/ blender disc and shaft, and will void warranty. Quaternary sanitizers may be acceptable if approved by f'REAL/ Foods. Call our Customer Support Center at 800-483-3218 for more information.
9. While 2 minute sanitize cycle timer counts down, clean f'REAL/ Brush and hands again with dishwashing liquid to ensure they are as clean as possible for Step 11, and then thoroughly rinse with warm water.
 10. When sanitize cycle ends, remove Sanitizing Cup from cup holder, and open front door of blender again.
 11. Use cleaned f'REAL/ Brush dipped frequently in Iodophor sanitizer solution from Sanitizing Cup to thoroughly apply sanitizing solution to:
 - a. First, the underside of metal cup lid. (Lift lid up along shaft to thoroughly apply sanitizer to underside of lid.);
 - b. And then, the top of metal cup lid. Be sure to apply solution to area touched when lifting the cup lid in prior step.
 12. Pour remaining sanitizing solution down blender's internal drain located in gray plastic blending chamber.
 13. Close front door firmly. Blender will automatically rinse off sanitized components.
 14. Rinse f'REAL/ Brush and Sanitizing Cup thoroughly with hot water. Allow to dry and save for next day's use.

Notice: To avoid compromising f'REAL/ Blender cleaning and sanitizing, do not use f'REAL/ Sanitizing Cup or f'REAL/ Brush on equipment other than f'REAL/ Blenders. Replace sanitizing brush every three (3) weeks with new f'REAL/ Brush provided in kit to be sure brush is in good condition. Order replacement cups, brushes and BTF Iodophor Sanitizer as they wear out or run out by calling f'REAL/ Customer Support at 800-483-3218.

* To confirm iodophor sanitizing solution is properly prepared, test strips are provided in vial with all sanitizer kits available from f'REAL/. To use test strips:

- a. Remove test strip from vial using dry fingers.
- b. Dip test strip into prepared iodophor sanitizing solution for 60 seconds without agitating, and then remove.
- c. Compare color of test strip to color comparison chart provided in vial.
- d. Colors in range from 12.5 ppm to 25 ppm confirm proper sanitizer concentration.



The National Food Laboratory, Inc.

6363 CLARK AVENUE, DUBLIN, CALIFORNIA 94568-3097
(925) 828-1440

Sanitation Monitoring of Milkshake Blenders

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Food Protection Program
Indiana State Dept. of Health

**For
f'Real! Foods, LLC**

**The National Food Laboratory
MH5123-1**

March 11, 2005

**By
Shaunti Luce
Laboratory Manager
Process Research & Microbiology**

Background:

F'Real! Foods, LLC requested the assistance of The NFL in conducting an experiment that will yield data to optimize the sanitation protocol of their milkshake blenders.

Objective:

To determine the microbial environment of the blending apparatus and housing over a 1-day period after blender apparatus after the blender is subjected to 1 milkshake product contaminated with *Enterobacter aerogenes*.

Materials:

F'Real! Foods, LLC provided their blenders as well as product for testing. There were three different varieties of product, Vanilla, Chocolate, and Strawberry. The NFL provided the materials needed for the swabbing.

Preparation of Culture: *Enterobacter aerogenes* (ATCC 13048) was inoculated into Tryptic Soy Broth and incubated at 35 °C for 18 hours. The concentration of this suspension was determined with a Petroff-Hauser counting chamber.

Experiment Protocol:

The experiment was conducted over 1 day, in a 30 °C incubator to stimulate the scenario for optimal microbial growth. The milkshake blender was cleaned and sanitized just once prior to beginning the experiment. 1 milkshake inoculated with *Enterobacter aerogenes* was blended, and then tested for Aerobic Plate Count (APC) and Coliforms. Swabs were taken just after the initial sanitation and then at 0, 4, 8, and 24 hours. There were 5 sampling sites for the swabs:

1. Blender shaft
2. Blender blade
3. Top of cup weight
4. Underside of cup weight
5. Walls of blending chamber

Each sampling site was divided into 4 quadrants, and each quadrant was swabbed on a rotating basis. Occasionally the drain was also swabbed. The swabs were also tested for Aerobic Plate Count and Coliforms. The results are listed in table 1.1.

Microbiological Methods:

For both the blended milkshake and the swabs serial dilutions were performed for both the APC and the Coliform analysis. Plate Count Agar was the media used for the APC; these plates were incubated at 35 °C for 48 hours. Violet Red Bile Agar was the media used for the Coliform analysis; these plates were incubated at 35 °C for 24 hours. After incubation the growth on the plates was counted and recorded.

Table 1.1

Inoculated Milkshake Coliform Count = 220 cfu/g

Coliforms cfu/area	Pre 1st Shake	Post 1st shake	4 hours	8 hours	24 hours
Blender shaft	<10	<10	<10	<10	<10
Blender blade	<10	<10	<10	<10	<10
Top of cup weight	<10	<10	<10	<10	<10
Underside of cup weight	<10	<10	<10	<10	<10
Walls of blending chamber	<10	<10	<10	<10	<10
Drain	<10	<10	<10	<10	<10

Conclusion:

The internal sanitation procedure in the milkshake machine was sufficient enough to not allow *Enterobacter aerogenes* to remain, after blending just one milkshake. The *Enterobacter aerogenes* that was in the blended milkshake did not carry over or remain in any of the areas swabbed and tested for Coliforms.

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6363 CLARK AVENUE, DUBLIN, CALIFORNIA 94568-3097
(925) 828-1440

Sanitation Monitoring of Milkshake Blenders

**For
f[®]REAL! Foods, LLC**

**The National Food Laboratory
MH5123-6.8**

April 4, 2005

**By
Shaunti Luce
Laboratory Manager
Process Research & Microbiology**

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**Food Protection Program
Indiana State Dept. of Health**

Background:

f'REAL! Foods, LLC requested the assistance of The NFL in conducting an experiment that will yield data to optimize the sanitation protocol of their milkshake blenders.

Objectives:

To determine the microbial environment of the blending apparatus and housing during actual field conditions over a 3 day period.

Materials:

f'REAL! Foods, LLC provided their blenders as well as product for testing. There were three different varieties of product, Vanilla, Chocolate, and Strawberry milkshakes. The NFL provided the materials needed for the swabbing.

Experiment Protocol:

The experiment was conducted over a period of 3 days at a store in Lee's Summit, Missouri. Two milkshake blenders at the store were cleaned and sanitized prior to beginning the experiment and again at the beginning of each new day, just after the 24th hour sampling from the prior day. This schedule is the same as the current field recommendation of once each 24 hours. Customers blended milkshakes in each of the two blenders, as they normally would on any other day. In addition to the milkshakes blended by customers each day, 4 were blended in each blender by the person gathering samples at the store, and tested for Aerobic Plate Count (APC) and Coliforms. On one of the two blenders, the milkshakes blended by the attendant had two Oreo type cookies added to them before blending to simulate the scenario where a customer might put something into the milkshake cup before blending it. These four milkshake samples on each blender were taken each day: From the first milkshake blended just after sanitation, and then at the 4th, 8th and 24th hours. Swabs were taken after the initial sanitation but before the first milkshake was run, and then right after the first milkshake was run, and at 4, 8, and 24 hours. There were 5 sampling sites for the swabs, each approximately 2 square inches in area:

1. Blender shaft
2. Top of cup weight
3. Blender blade
4. Underside of cup weight
5. Walls of blending chamber

The swabs were also tested for Aerobic Plate Count and Coliforms. The results for the product and swabs are listed in tables 1.1 through 1.4

Microbiological Methods:

For both the blended milkshake and the swabs, serial dilutions were performed for both the APC and the Coliform analysis. Plate count agar was the media used for the APC; these plates were incubated at 35 °C for 48 hours. Violet Red Bile Agar was the media used for the Coliform analysis; these plates were incubated at 35 °C for 24 hours. After incubation the growth on the plates was counted and recorded. The results are listed in tables 1.1 through 1.4.

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Table 1.1 – Milkshake Analysis

Milkshakes (cfu/g)	Post 1st Shake		4 hours		8 hours		24 hours	
	APC	Coliforms	APC	Coliforms	APC	Coliforms	APC	Coliforms
Left blender								
Day 1	100	<10	90	<10	90	<10	No sample taken	
Day 2	80	<10	70	<10	160	<10	No sample taken	
Day 3	130	<10	No sample taken		No sample taken		No sample taken	
Right blender (cookies added)								
Day 1	3200	<10	60	<10	230	<10	No sample taken	
Day 2	90	<10	140	<10	290	<10	No sample taken	
Day 3	250	<10	No sample taken		No sample taken		No sample taken	

Table 1.2 – Day 1 Swabs

Day 1 Swabs (cfu/area)	Pre 1st Shake		Post 1st shake		4 hours		8 hours		24 hours	
	APC	Coliforms	APC	Coliforms	APC	Coliforms	APC	Coliforms	APC	Coliforms
Left blender										
Blender shaft	<10	<10	<10	<10	<10	<10	<10	<10	<10	<10
Top of cup weight	<10	<10	<10	<10	<10	<10	<10	<10	<10	<10
Blender blade	<10	<10	<10	<10	<10	<10	<10	<10	<10	<10
Underside of cup weight	40	<10	<10	<10	<10	<10	<10	<10	<10	<10
Walls of blending chamber	<10	<10	10	<10	<10	<10	<10	<10	<10	<10
Right blender (cookies added)										
Blender shaft	<10	<10	<10	<10	<10	<10	<10	<10	<10	<10
Top of cup weight	<10	<10	<10	<10	<10	<10	<10	<10	<10	<10
Blender blade	<10	<10	<10	<10	<10	<10	<10	<10	<10	<10
Underside of cup weight	1200	<10	<10	<10	270	<10	210	<10	<10	<10
Walls of blending chamber	<10	<10	10	<10	10	<10	<10	<10	<10	<10

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Table 1.3 – Day 2 Swabs

Day 1 Swabs (cfu/area)	Pre 1st Shake		Post 1st shake		4 hours		8 hours		24 hours	
	APC	Coliforms	APC	Coliforms	APC	Coliforms	APC	Coliforms	APC	Coliforms
Left blender										
Blender shaft	<10	<10	<10	<10	<10	<10	<10	<10	<10	<10
Top of cup weight	<10	<10	<10	<10	<10	<10	<10	<10	<10	<10
Blender blade	<10	<10	<10	<10	<10	<10	<10	<10	<10	<10
Underside of cup weight	<10	<10	<10	<10	<10	<10	<10	<10	<10	<10
Walls of blending chamber	<10	<10	<10	<10	<10	<10	10	<10	<10	<10
Right blender (cookies added)										
Blender shaft	<10	<10	<10	<10	<10	<10	<10	<10	<10	<10
Top of cup weight	<10	<10	<10	<10	<10	<10	<10	<10	<10	<10
Blender blade	<10	<10	<10	<10	<10	<10	220	<10	<10	<10
Underside of cup weight	<10	<10	<10	<10	<10	<10	<10	<10	<10	<10
Walls of blending chamber	<10	<10	<10	<10	<10	<10	<10	<10	<10	<10

Table 1.4 – Day 3 Swabs

Day 1 Swabs (cfu/area)	Pre 1st Shake		Post 1st shake		4 hours		8 hours		24 hours	
	APC	Coliforms	APC	Coliforms	APC	Coliforms	APC	Coliforms	APC	Coliforms
Left blender										
Blender shaft	<10	<10	<10	<10	10	<10	10	<10	<10	<10
Top of cup weight	<10	<10	<10	<10	<10	<10	80	<10	<10	<10
Blender blade	<10	<10	<10	<10	<10	<10	50	<10	<10	<10
Underside of cup weight	<10	<10	<10	<10	10	<10	80	<10	<10	<10
Walls of blending chamber	<10	<10	<10	<10	<10	<10	<10	<10	<10	<10
Right blender (cookies added)										
Blender shaft	<10	<10	<10	<10	<10	<10	40	<10	<10	<10
Top of cup weight	<10	<10	<10	<10	<10	<10	<10	<10	<10	<10
Blender blade	<10	<10	<10	<10	<10	<10	<10	<10	<10	<10
Underside of cup weight	<10	<10	<10	<10	<10	<10	<10	<10	<10	<10
Walls of blending chamber	<10	<10	<10	<10	20	<10	30	<10	<10	<10

Conclusion:

CFR Title 7, Part 58, Section 648 - Microbiological requirements for ice cream - states:

"The finished product shall contain not more than 50,000 bacteria per gram as determined by the standard plate count, and shall contain not more than 10 coliform organisms per gram for plain and not more than 20 coliform per gram in chocolate, fruit, nut or other flavors in three out of five samples."

With the swabbed areas of approximately 2 square inches in each of the five locations sampled, and a typical residual thickness of 1/32 inch, as observed, the sampled residue measures approximately 1 gram in each instance. This allows direct comparison of the observed counts to the CFR standards per gram for microbial activity in ice cream.

In all sample instances, coliform organisms per gram were less than 10, and therefore fall within the CFR limits.

There were very low if any levels of aerobic bacteria seen in virtually all test swab locations. In the few cases where there were measurable levels, there was not a single case of a consistent increase overtime. That is, in every case where there was growth from one time period to the next, there was a decrease in the subsequent time period. In all sample instances, APC were more than a full order of magnitude less than 50,000, with the highest APC observed over the three day period being 1,200, and therefore well within the 50,000 cfu/gram CFR limits. The levels of bacteria are very low, sporadic and do not increase over time, which would be an indication that the rinsing procedures are sufficient to inhibit the growth of bacteria. The levels indicate that the automated internal rinsing is sufficiently rinsing the machine after each milkshake is blended to inhibit the growth of bacteria.

There was no significant difference in APC between the blender that had milkshakes with cookies added versus the blender without cookies added. Both blenders performed equally well, with no evidence of growth of bacteria.

When the results from this in-field test are compared with the in-lab test, an interesting observation emerges. The results of the in-field testing are generally significantly lower in APC than the in-lab testing. This can be attributed to an improved cleaning and sanitizing protocol used for the in-store testing versus the in-lab testing. A more thorough job of cleaning the blenders was done before sanitizing the blenders for the in-store test, and this caused a significant improvement in the results. The new cleaning and sanitizing protocol followed for the in-field testing is attached at the end of this report. It is recommended that this improved protocol be practiced for in-field installations of the blender in the future.

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Indiana State Dept. of Health**

Account Name	Shipping Street	Shipping City	Shipping State/Province	Shipping Zip/Postal Code	Phone
Circle K 023	4054 E. Southport Road	Indianapolis	IN	46237	(317) 782-4389
Circle K 029	2510 S. Leonard Springs Road	Bloomington	IN	47403	(812) 825-7866
Circle K 2285	11601 Allisonville Road	Fishers	IN	46038	(317) 577-9160
Circle K 2304	9611 Allisonville Road	Fishers	IN	46038	(317) 577-9451
Circle K 065	10080 U. S. 31 P.O. BOX 295	Taylorsville	IN	47280	(812) 526-9119
Circle K 2205	702 S. Washington	Marion	IN	46952	(765) 668-8497
Circle K 2211	103 E. Marion	Converse	IN	46919	(765) 395-5622
Circle K 2216	127 N. Main Street PO Box 516	Summitville	IN	46070	(765) 536-2085
Circle K 2218	101 N. First Street	Van Buren	IN	46991	(765) 934-3234
Circle K 2219	3245 S. Washington	Marion	IN	46952	(765) 664-3500
Circle K 2228	3706 Charlestown Road	New Albany	IN	47150	(812) 949-9329
Circle K 2232	612 Oak Street	Seymour	IN	47274	(812) 523-1130
Circle K 2234	1219 Clifty Drive	Madison	IN	47250-1615	(812) 265-2245
Circle K 2248	2304 Sherman Blvd.	Ft. Wayne	IN	46808	(260) 471-9631
Circle K 2262	3105 First Avenue North	Evansville	IN	47711	(812) 424-7517
Circle K 013	680 N. State Road 39	Martinsville	IN	46151	(765) 342-5470
Circle K 020	148 E. Morgan	Spencer	IN	47460	(812) 829-4641
Circle K 2269	801 S Washington Street	Crawfordsville	IN	47933	(765) 361-9575
Circle K 2274	1360 North Green	Brownsburg	IN	46112	(317) 858-7204
Circle K 026	401 E. National Highway	Washington	IN	47501	(812) 254-3367
Circle K 2279	9599 N Meridian Sreet	Indianapolis	IN	46260	(317) 846-9748
Circle K 2284	8924 E 116th Street	Fishers	IN	46038	(317) 570-1068
Circle K 046	339 S. Main Street	Martinsville	IN	46151	(765) 342-7075
Circle K 047	714 W. Main Street	Austin	IN	47102	(812) 794-2131
Circle K 048	201 W. 17th Street	Bloomington	IN	47401	(812) 331-1823
Circle K 055	9400 State Route 144	Martinsville	IN	46151	(317) 422-8911
Circle K 060	1644 Central Avenue	Columbus	IN	47201	(812) 378-1765
Circle K 084	3900 1Street Avenue	Evansville	IN	47710	(812) 425-6927
Circle K 091	7 North Fulton	Evansville	IN	47710	(812) 461-0074
Circle K 120	4101 Highway 41 N	Evansville	IN	47711	(812) 424-6497
Circle K 121	2105 E King Street	Franklin	IN	46131	(317) 738-4406
Circle K 130	414 Highway 160 West	Henryville	IN	47126	(812) 294-4560
Circle K 142	1201 W. Columbia	Evansville	IN	47710	(812) 424-6128
Circle K 093	300 S Green River Road	Evansville	IN	47715	(812) 477-4332
Circle K 2203	901 E. Bradford	Marion	IN	46952	(765) 668-7728
Circle K 2297	3801 South Post	Indianapolis	IN	46239	(317) 862-7704
MotoMart 3202	6328 East Lloyd Expressway	Evansville	IN	47715-2720	(812) 476-8621
Hucks 362	631 W. Fourth St.	Mt. Vernon	IN	47620	(812) 838-8460
Hucks 272	Hwy 66 Box 7777	Newburgh	IN	47630	(812) 858-9860
Hucks 283	102 E. Lincoln Ave	Chandler	IN	47610	(812) 925-3281
Hucks 325	11 West Main	Austin	IN	47102	(812) 794-6610
Hucks 338	2816 N. Sixth	Vincennes	IN	47591	(812) 886-4323
Hucks 363	880 East Mishawaka Rd	Elkhart	IN	46516	(574) 293-7061
Hucks 289	208 S. State Rd. 145	French Lick	IN	47432	(812) 936-9400
Hucks 298	322 East Broadway	Fortville	IN	46040	(317) 485-7774
Hucks 286	230 Third Ave	Jasper	IN	47546	(812) 481-1016
Hucks 290	1521 Hart St.	Vincennes	IN	47591	(812) 886-9952
Hucks 293	515 West Main	Greentown	IN	46936	(765) 628-3543
Hucks 135	1515 Washington Ave.	Vincennes	IN	47591	(812) 882-3855
Hucks 284	819 Main St.	Mt. Vernon	IN	47620	(812) 838-4449
Hucks 301	9823 N. State Rd. 9	Hope	IN	47246	(812) 546-4449
Hucks 323	US Hwy 41 & SR 168/RR 1 Box 355	Fort Branch	IN	47648	(812) 753-4946
Hucks 285	17 West Main St.	Petersburg	IN	47567	(812) 354-3739
Pilot 445	243 Melton Road	Burns Harbor	IN	46304	(219) 787-5705
Pilot 447	1042 East Warrenton Road Route 2 Box 109E	Haubstadt	IN	47639	(812) 868-1048
Pilot 448	18011 Colorado Street	Hebron	IN	46341	(219) 696-8265
Pilot 478	6921 South SR 66	Leavenworth	IN	47137	(812) 739-2002
Village Pantry 00588	1101 S E Street	Richmond	IN	47374	(765) 966-1254
Village Pantry 00571	899 E. Main Street	Greenwood	IN	46143	(317) 887-6704
Village Pantry 00401	8772 East 96th Street	Fishers	IN	46037	(317) 578-8837
Village Pantry 00585	5960 East Thompson Road	Indianapolis	IN	46237	(317) 782-8165

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Indiana State Dept. of Health



State of Wisconsin
Jim Doyle, Governor

WISC

dk

Department of Agriculture, Trade and Consumer Protection

Rod Nilsestuen, Secretary

4 April 2005

Mr. Jim Farrell
F"Real/ Foods, LLC
37 Avenida de Orinda
Orinda CA 94563

Re: Milk Shake Machines in
Kwik Trips.

Dear Sir:

You have submitted a study done by The National Food Laboratory of Dublin, California, as evidence that your frozen beverage blender, Model FRLB2, qualifies for a variance from the cleaning and sanitizing schedule in Wisconsin's Food Code, Appendix 75, 4-602.11(D). You have claimed that your evidence qualifies you for a variance to being cleaned and sanitized only once each 24 hours under the provisions for variance in Wisconsin's Food Code Appendix 75, 4-602.11(D)(6).

This variance is granted with the following conditions:

- The blender, Model FRLBR2, must be cleaned and sanitized no less than every 24 hours according to the protocol for cleaning and sanitizing set forth in the f'Real Model FRLBR 2 Installation and Operation Guide, revision D. This includes the use of the specified sanitizing agent in the specified amounts.
- The blender unit rinse water be heated by the unit to at least 125° F. according to the specifications in the Installation and Operation Guide.
- The unit be used only for the intended purpose with the intended product.

Any changes to methods of operation, methods of cleaning and/or sanitizing, or product line may result in the revocation of this variance. Any changes should be reported to this office as soon as possible.

State Inspectors and Agent Program Inspectors will perform inspections periodically to verify compliance. If you have any questions, feel free to contact me at (608) 224-4715.

Sincerely,

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JUN 12 2008

Arthur J. Ness, R.S.
Food Scientist
Division of Food Safety
Wisconsin Department of Agriculture, Trade, and
Consumer Protection.

Food Protection Program
Indiana State Dept. of Health

cc: Mike Barnett, Food Safety Supervisors,
Agent Programs, Lyle Anthony (Kwik
Trip), file.

Agriculture generates \$51.5 billion for Wisconsin